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Remarks

Claims 36-41, 43-50, 53-66, 68, and 70-77 were pending. By way of this response, claims 36, 39, 41, 43-46, 59, 60, 64, and 74 have been amended, claim 38 has been cancelled, and claims 78-86 have been added. Support for the amendments to the claims can be found in the application as originally filed, and no new matter has been added. Accordingly, claims 36, 37, 39-41, 43-50, 53-66, 68, and 70-86 are currently pending.

Applicant acknowledges that the objection to the Declaration, the rejections under 35 U.S.C. § 112, the rejections under 35 U.S.C. § 102 with respect to Hanssler et al. (DE 3309765), Kelly et al. (U.S. 5,118,493), and Dean et al. (U.S. 6,242,442), and the double patenting rejection have been withdrawn.

Rejections Under 35 U.S.C. § 102

Claims 36, 37, 41, 43, 44, 46-50, 53, 54, 57, and 59 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by FR 2272684. Claims 36-41, 43, 44, 47-50, 53-58, 70-75, and 77 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Garst (U.S. 6,294,563). Claims 60-66, 68, 72, and 73 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Gil et al. (U.S. 6,294,553).

Based on the foregoing, applicant acknowledges that the subject matter of claim 38 is not anticipated by FR 2272684 and that the subject matter of claim 46 is not anticipated by Garst

or Gil et al. Applicant respectfully traverses the rejections as they relate to the amended claims and the new claims.

Claims 36 and 60 have been amended to include the subject matter of claims 38. Claim 74 has been amended to include the subject matter of claim 46. The claims have been amended as set forth above to expedite the allowance of the claims directed to particular embodiments of the invention. The amendments to the claims do not evidence applicant's disclaimer from the scope of equivalents of subject matter not explicitly mentioned in the claims.

Applicant submits that FR 2272684 does not disclose, teach, or suggest the present invention. For example, FR 2272684 does not disclose, teach, or even suggest a composition comprising an alpha-2 adrenergic agonist, as recited in claim 36. In addition, FR 2272684 does not disclose, teach, or even suggest a composition comprising an efficacy enhancing component in an amount greater than 0.2% (w/v) and less than about 10% (w/v), as recited in claim 36.

Furthermore, applicant respectfully disagrees that claim 59 is anticipated by FR 2272684. FR 2272684 discloses a composition containing an antibiotic, not an adrenergic agonist, as recited in claim 59.

As to new claims 78-86, applicant submits that FR 2272684 does not disclose, teach, or even suggest a liquid composition comprising a therapeutic component and an efficacy enhancing component provided in an amount to form a complex which contributes to a lower or reduced osmotic pressure of the

composition relative to a substantially identical composition in which the therapeutic component is not complexed with the efficacy enhancing component.

In view of the above, applicant submits that the present claims, in particular claims 36, 37, 41, 43, 44, 46-50, 53, 54, 57, 59, and 78-86, are not anticipated by FR 2272684 under 35 U.S.C. § 102, and are unobvious from and patentable over FR 2272684 under 35 U.S.C. § 103.

Regarding the rejection of the claims over Garst, applicant submits that Garst does not specifically disclose, teach, or suggest the present invention. For example, Garst does not specifically disclose, teach, or even suggest a composition comprising a therapeutic component that comprises an alpha-2 adrenergic agonist and an efficacy enhancing component provided in an amount greater than 0.2% (w/v) and less than about 10% (w/v), as recited in claim 36. The prostaglandins disclosed by Garst are provided in amounts less than 0.2% (column 8, lines 63-64).

In addition, Garst does not specifically disclose, teach, or even suggest a composition comprising an adrenergic agonist and an efficacy enhancing component provided in an amount that is effective to form an ion-pair complex with the adrenergic agonist, which remains substantially intact in a high dielectric constant solvent, as recited in claim 59.

With regard to claim 74, applicant submits that Garst does not specifically disclose, teach, or even suggest a composition

that includes an efficacy enhancing component that comprises a linoleic acid component.

Further, with regard to new claims 78 to 86, applicant submits that Garst does not specifically disclose, teach, or even suggest a liquid composition comprising a therapeutic component and an efficacy enhancing component provided in an amount effective to form a complex, which is effective to provide a lower or reduced osmotic pressure to the liquid composition relative to a substantially identical composition in which the therapeutic component is not complexed with the efficacy enhancing component.

In view of the above, applicant submits that the present claims, in particular claims 36-41, 43, 44, 47-50, 53-58, 70-75, and 77-86, are not anticipated by Garst under 35 U.S.C. § 102, and are unobvious from and patentable over Garst under 35 U.S.C. § 103.

Regarding the rejection of the claims over Gil et al., applicant submits that Gil et al. does not specifically disclose, teach, or suggest the present invention. For example, Gil et al. does not specifically disclose, teach, or even suggest a composition comprising an ion-pair complex including a therapeutic component and an efficacy enhancing component, as recited in certain of the presently rejected claims.. Moreover, Gil et al. does not specifically disclose, teach, or even suggest a composition in which an efficacy enhancing component is present in an amount greater than 0.2% (w/v) and less than about 10% (w/v), as recited in certain of the presently rejected claims. Further, Gil et al. does not specifically disclose,

teach, or even suggest a composition comprising a linoleic acid component, as recited in certain of the presently rejected claims. As to new claims 78-86, applicant submits that Gil et al. does not specifically disclose, teach, or even suggest a liquid composition comprising a therapeutic component and an efficacy enhancing component provided in an amount effective to form a complex, which is effective to provide a lower or reduced osmotic pressure to the liquid composition relative to a substantially identical composition in which the therapeutic component is not complexed with the efficacy enhancing component.

In view of the above, applicant submits that the present claims, in particular claims 60-66, 68, 72, 73, and 78-83 are not anticipated by Gil et al. under 35 U.S.C. § 102, and are not unobvious from and patentable over Gil et al. under 35 U.S.C. § 103.

In addition, applicant submits that the present claims are unobvious from and patentable over any and all of the prior art, taken in any combination, under 35 U.S.C. § 103.

Rejections under 35 U.S.C. § 103

Claims 45 and 76 have been rejected under 35 U.S.C. § 103 as allegedly being obvious over the combination of Garst in view of Dean et al. (U.S. 6,242,442).

Applicant respectfully traverses the rejection as it applies to the present claims.

Applicant submits that the combination of Garst and Dean et al. do not specifically disclose, teach, or even suggest the present invention. For example, this combination of references does not disclose, teach, or suggest a composition comprising an ion-pair complex of a therapeutic component and an efficacy enhancing component, where the efficacy enhancing component is provided in an amount greater than 0.2% (w/v) and less than about 10% (w/v), as recited in claim 45 due to its dependency from claim 36, or a composition comprising a therapeutic component comprising a 5-bromo-6-(2-imidazolyl-2-ylamino) quinoxaline and an efficacy enhancing component comprising a linoleic acid component, as recited in claim 76 due to its dependency from claim 74.

In view of the above, applicant submits that the present claims, and in particular claims 45 and 76, are unobvious from and patentable over the combination of Garst and Dean et al. under 35 U.S.C. § 103.

In addition, each of the present dependent claims is separately patentable over the prior art. For example, none of the prior art disclose, teach, or even suggest the present compositions including the additional feature or features recited in any of the present dependent claims. Therefore, applicant submits that each of the present claims is separately patentable over the prior art.

In conclusion, applicant has shown that the present claims are not anticipated by and are unobvious from and patentable over the prior art under 35 U.S.C. §§ 102 and 103. Therefore, applicant submits that the present claims, that is claims 36,

37, 39-41, 43-50, 53-66, 68, and 70-86 are allowable, and respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date:

February 13, 2004

Respectfully submitted,



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